

REMARKS

Reconsideration of the application is requested. Claims 1, 4-10, 13, 15, 19, 31, 32, 35, 37-39, and 48-51 are now in the application. Claims 1, 4, 37-39, 48, and 49 have been amended; claims 2, 3, 11, 12, 16-18, 20-30, 33, 34, 36, and 40-47 have been canceled; and claim 51 has been added. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Claim Rejections Under 35 USC § 101

Claims 1, 4-10, 13, 15, 19, 30-32, 35, 37-39, 41, and 46-50 were rejected under 35 USC § 101 as being drawn to non-statutory subject matter. In particular, it was asserted that independent claims 30 and 41 each “positively recites part of a human, *i.e.* the implant being fixed to only the first bone.” Applicant respectfully disagrees. The mere mention of a part of a human does not give rise to impermissibly claiming the human body. In this regard, Applicant notes that no part of the human body is positively claimed. The bones described in the claims are never positively claimed. Rather, the bones are the work piece with which the positively claimed device interacts. See MPEP § 2115. The bones are only inferentially introduced and not positively claimed. Accordingly, the claims do not positively claim natural subject matter.

In any event, claims 30 and 41 (as well as dependent claims 30, 46, and 47) have been canceled. However, the claims were not canceled for reasons relating to the Section 101 rejection. Independent claims 30 and 41 were canceled in favor of new claim 51, which clarifies the invention as claimed.

Claim Rejections Under 35 USC § 112

Claims 1, 4-10, 13, 15, 19, 30-32, 35, 37-39, 41, and 46-50 were rejected under the second paragraph of 35 USC § 112 as being indefinite. Without conceding the validity of this rejection and as noted above, independent claims 30 and 41 (as well as dependent claims 30, 46, and 47) have been cancelled. According the indefiniteness rejection is now moot.

Claim Rejections Under 35 USC § 103(a)

Claims 1, 8, 9, 13, 15, 19, 30-32, 35, 37-39, 41, and 43-45, and 47-50 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,008,433 to Stone (“Stone”) in view of U.S. Patent No. 5,609,635 to Michelson (“Michelson”) and U.S. Patent No. 6,066,175 to Henderson *et al.* (“Henderson”). Claims 4-7 were rejected under 35 USC § 103(a) as being unpatentable over Stone in view of Michelson and Henderson further in view of U.S. Patent No. 4,394,370 to Jefferies (“Jefferies”). Claim 10 was rejected under 35 USC § 103(a) as being unpatentable over Stone in view of Michelson and Henderson further in view of U.S. Patent No. 5,669,909 to Zdeblick *et al.* (“Zdeblick”). For reasons set forth below, Applicant respectfully submits that these rejections should be withdrawn.

As an initial matter, claims 30, 41, 46, and 47 have been cancelled without prejudice and without conceding the rejection, thereby rendered the rejection to these claims as moot. Furthermore, the references are described individually only to clarify what each reference teaches. Thus, presentation of individual descriptions of the references is not and should not be interpreted as an attempt “to argue the references separately.” Finally, Applicant notes that Stone, Michelson, Henderson, Jefferies and Zdeblick have been discussed in prior Responses. This discussion is incorporated herein by reference and will not be repeated in this interest of brevity.

New independent claim 51 is directed to an implantable device for changing a spatial relationship between a first bone and a second bone in a joint from a first position to a second position while allowing relative movement between the first and second bones. The implantable device comprises a first surface configured to abut the first bone; a second surface configured to abut the second bone; a body interconnecting said first surface and said second surface; a side surface spanning said first surface and said second surface; and at least one channel extending through said first surface to said side surface. Each of said at least one channel is configured and dimensioned to receive a fastener for fixedly connecting said body to the first bone. The device is free of any channels extending through said second surface to said side surface and configured and dimensioned to receive a fastener for fixedly connecting said body to the second bone.

Thus, claim 51 recites structural elements that at least one channel extends through said first surface to said side surface, with each of said at least one channel configured and dimensioned to receive a fastener for fixedly connecting said body to the first bone. Claim 51 further recites that the device is free of any such channels extending through said second surface to said side surface and configured and dimensioned to receive a fastener for fixedly connecting said body to the second bone.

With respect to Stone, when considered as a whole, there is nothing to teach or suggest the structure as set forth in claim 51, *e.g.* the structure of one surface is different than the structure of the other surface so that one surface is fixed to the bone while the other is free. When Stone is considered in its entirety, there is nothing to indicate that it is any different than any other osteotomy device in this regard. As previously noted, in practice an osteotomy device must be secured on both the superior and inferior surfaces. As discussed in Applicant's Declaration under Rule 1.132 submitted June 12, 2007, one of ordinary skill in the art, such as an orthopedic surgeon, would know that an osteotomy device needs to be fixed on both sides to the bone in which the device is inserted. Furthermore, an orthopedic surgeon and one of ordinary skill in the art would know this regardless of the ambiguous language used in Stone. To date, there is nothing on the record that the previously submitted declaration should not be considered or otherwise discounted.

Furthermore, claim 51 specifically recites at least one channel extending through said first surface to said side surface, with each of said at least one channel configured and dimensioned to receive a fastener for fixedly connecting said body to the first bone; and the device is free of any such channels extending through said second surface to said side surface and configured and dimensioned to receive a fastener for fixedly connecting said body to the second bone. Such structure is missing from Stone.

Similarly, Henderson teaches an implant with a porous surface or smooth-but-fastened surface for immobilizing both sides of a joint. Michelson teaches a porous implant for encouraging bone in-growth that is used immobilize both sides of a joint. In summary, Henderson and Michelson are both fusion devices, with no movement between the two bones, while the instant invention with the recited structure permits movement between the two bones.

Stone in view of Michelson and Henderson does not teach or suggest the invention as recited in claim 51. As set forth in claim 51, the as-claimed invention is more than a modification with an obvious omission of a part. As an initial matter, there is no motivation to omit the part. When considered as a whole, one of ordinary skill would not have any reason (other than impermissible hindsight) to modify Stone, Michelson and Henderson to obtain the invention as set forth in claim 51. In any event, claim 51 recites structures that are not taught or suggested by the prior art: a surface that has a channel for a fastener while the other surface is free of any such channels. The prior art teaches a device that is either smooth and secured with a fastener or a rough surface that is mechanically held by the surface qualities. In both situations, the devices suggested by the prior art are not applicable to a joint wherein one bone is left to articulate relative to the implant.

Jefferies and Zdeblick do nothing to remedy the deficiencies of Stone, Michelson, and Henderson. Accordingly, none of the references, whether taken alone or in any combination, either show or suggest the features of claim 51. Therefore, claim 51 is patentable over the art. And, because all of the dependent claims ultimately depend from claim 51, they are believed to be patentable as well at least for the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the §103 rejections.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Fees for an extension of time and an RCE are believed to be due for this submission and are being paid by credit card. However, please charge any required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No.780-A03-021-5).

Respectfully submitted,

/ Paul D. Bianco /

Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@fggbb.com